

## REMARKS

By way of summary, Claims 1-15 and 17-35 were pending in this application prior to this Response. In the outstanding Office Action of March 24, 2008, the Examiner rejected Claims 1-10, 20-25, and 27-35 under 35 U.S.C. § 103(a) as being unpatentable over Ginn (U.S. Pub. No. 2003/0050665) and Johnson (U.S. Patent No. 6,485,504); the Examiner also rejected Claims 11-15 and 17-19 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view Johnson in further view of Pierson, III (U.S. Patent No. 6,663,633).

### **I. § 103(a) Claim Rejections**

#### **A. All Claim Rejections Fail to Provide Proper *Graham* Factual Inquiries and Fail to Articulate Findings under the *KSR* Examination Guidelines**

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* ("Examination Guidelines"), which were published in the Federal Register Vol. 72, No. 195 (Docket PTO-P-2007-0031) on October 10, 2007, apply the Supreme Court's decision in *KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) with regard to the issue of obviousness under 35 U.S.C. § 103(a) in relation to prior art. Applicant submits that the outstanding Office Action fails to satisfy the Examiner's burden in establishing an obviousness rejection.

Under the Examination Guidelines, and as reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

The Examination Guidelines confirms the role of Patent Office personnel as fact finders:

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have

known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

72 Fed. Reg. 57527 (Oct. 10, 2007).

The Examination Guidelines further provide that “Once the Graham factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.” *Id.* “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 57528-57529 (internal citations omitted). Under the Examination Guidelines, a rejection must offer specific support for the following rationales Examiners may use to show obviousness:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

*Id.* at 57529.

The March 24, 2008 Office Action fails to set forth the level of ordinary skill in the pertinent art, or who qualifies as one of ordinary skill in the field. Applicant submits that without such a finding, the Examiner’s combinations are improper, as the Examiner has not established that the references proposed by the combinations would be known to one of ordinary skill in the art, nor that one of ordinary skill would have the requisite knowledge and ability to make the desired combinations.

Moreover, the Examiner has failed to articulate specific rationales for the proposed combinations of references, and has failed to provide explicit explanations supporting the obviousness rejections. The Examiner summarily concludes that “[i]t would have been obvious to one of ordinary skill in the art at the time of invention to modify Ginn by having the distal end of the coil be releasably engaged to the elongate body, as taught by Johnson, in order to effectively narrow the coil in diameter to facilitate deployment and also to minimize damage to tissue and allow flexibility and movement by the patient without disturbing the healing process.” Office Action at 4. Similarly, with respect to Claims 11-15 and 17-19, the Examiner remarks: “[i]t would have been obvious to one of ordinary skill in the art at the time of invention to provide a second coil in the delivery member to the septa of the patent foramen ovale, as taught by Pierson, to Ginn and Johnson in order to provide a more secure closure by covering more surface area of the tissue.” Office Action at 5. These are conclusory statements regarding the combinability of the cited prior art references; the Examiner has not (1) identified the knowledge one skilled in the art would possess, (2) described what modifications the skilled person would need to make to combine the prior art references, or (3) discussed whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant submits that the Examiner’s obviousness rejections are improper. More specific details relating to these missing inquiries and missing articulated findings are discussed in more detail below, along with Applicant’s reasoned statements explaining why Applicant’s claims are nonobvious over the cited art.

**B. Independent Claims 1, 20, and 31 Are Not Rendered Obvious over Ginn (U.S. Pub. No. 2003/0050665) in view of Johnson (U.S. 6,485,504)**

The outstanding Office Action rejected independent Claims 1, 20, and 31 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Johnson. As explained in detail below, Applicant asserts that the claimed inventions recited in Claims 1, 20, and 31 are not obvious because: (1) modifying Ginn with Johnson in the manner suggested by the Examiner would render the Ginn invention inoperable; (2) Johnson is in a different field of endeavor, and is not an analogous invention and thus is an inappropriate § 103(a) reference; (3) explicit language in Ginn teaches away from the claimed combination; and (4) even assuming that Johnson and Ginn are properly combinable, the resulting combination of does not teach or suggest all elements of the claimed invention.

**1. Ginn and Johnson Are Not Properly Combinable**

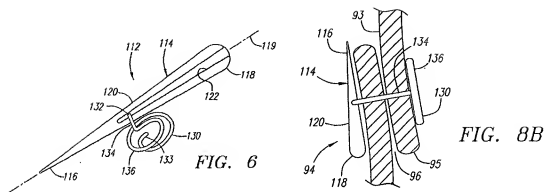
Section 2143.01.V of the M.P.E.P. instructs that a proposed modification of a prior art reference in view of another reference cannot render the modified invention incapable of performing its intended purpose.<sup>1</sup> Because the modifications to Ginn in view of Johnson as suggested by the Examiner would render Ginn inoperable for closing a PFO, a person having ordinary skill in the PFO art would not have modified Ginn in view of Johnson, as there would be no reasonable expectation of success. The combination is therefore an improper basis for an obviousness rejection.

There are two features of the Ginn invention that must exist in order for the invention to be operable. The first requirement is that the distal end of the filament cannot be released from the tissue piercing structure. The second requirement is that the tissue piercing structure of Ginn cannot be withdrawn from the septa or heart.

In order for Ginn to function properly the distal end of the filament 132 must not release from the tissue piercing structure 114. Ginn Fig. 6 and 8B (reproduced below). The Ginn invention closes a PFO by clamping or “sandwiching” the flaps of a PFO together. On one side of the sandwich is the tissue piercing structure, and on the other side is a locking device (in one embodiment, the coiled portion of the filament acts as the locking device). The portion of the filament that extends through the septa secures these two sides against the septa. Ginn at p. 2, para. [0022] (“[a] locking element may be secured to the filament, the locking element engaging the proximal surface of the flap of tissue to *secure the flap of tissue between the needle and the locking element*” (emphasis added)); see Ginn Figs. 4B, 5D, 6 and 8B. Ginn Figs. 6 and 8B are reproduced below; notice that on one side of the PFO “sandwich” is a tissue piercing structure 114, and on the other side is the coiled filament. If the traverse portion of the filament 134 were disengaged with the tissue piercing structure the invention of Ginn would not close a PFO.

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<sup>1</sup> M.P.E.P. § 2143.01.V (“If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”); see also, *id.* at 2143.01.VI (“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.”).



Given this understanding of Ginn's functionality, it becomes clear that if the distal end of the filament were ever disengaged from the tissue piercing structure, one or both sides of the sandwich would become loose and the septa would no longer be clamped shut. Yet this is exactly the modification the Examiner proposes: "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to modify Ginn by having the *distal* end of the coil be *releasably* engaged to the elongated body, as taught by Johnson . . ." Office Action at 4 (emphasis added). Further, the Examiner asserts: "Ginn discloses the claimed invention except for . . . *releasing the distal end of the coil*," *Id.* (emphasis added). The conclusion drawn from these two statements is that Ginn could be modified in view of Johnson so that the distal end of the coil is released. However, as just discussed, if the distal end 132 of the coil releases, Ginn would be rendered unsatisfactory for its intended purpose: the only structure in the Ginn invention that is connected with the tissue piercing structure is the distal end of the filament.

A second requirement that must be met in order for the invention of Ginn to be operable is that the tissue piercing structure must remain inside the heart; more specifically, it cannot be withdrawn from the septa of the PFO. Explicit language in Ginn supports this claim: "[after] the needle is directed entirely into the second chamber," "the filament may then be pulled . . . . As the filament is pulled, the blunt tip of the needle may engage a distal surface of the flap of tissue, thereby preventing the needle from being pulled back through the flap of tissue." Ginn at p. 2, para. [0020-0021].

If the tissue piercing structure of Ginn is withdrawn, at least one side of the sandwich formed by the combination of filament, locking device (or coiled filament) and tissue piercing structure would be missing and Ginn would again be inoperable. However, this is the modification the Examiner suggests: "Ginn discloses the claimed invention except for . . .

retracting the tissue piercing structure (or elongate body) from the septum primum and septum secundum . . . .” Office Action at 4. The Examiner then claims that Johnson teaches “retracting the elongate body from the tissue to allow the distal end of the coil to exit the opening of the elongate body . . . .” *Id.* These two statements imply that because Ginn does not disclose retracting the tissue piercing structure (or elongate body), but Johnson teaches that missing limitation, that Ginn should be modified in view of Johnson so that the tissue piercing structure is retracted from the septa. If such a modification of Ginn were made, it would again render Ginn unsatisfactory for its intended purpose: without the tissue piercing structure remaining inside the heart acting as one side of the sandwich, Ginn would no longer function to close a PFO.

For these reasons, Applicant submits that the Examiner’s obviousness rejection over Ginn in view of Johnson is improper, and the rejections of the claims based on this combination be withdrawn.

**2. Johnson is in a Different Field of Endeavor And Not An Analogous Invention**

Typically a reference forming the basis of a § 103(a) obviousness rejection comes from the Applicant’s field of endeavor. Although it is permissible to cite to a reference outside the Applicant’s field, the Examination Guidelines teach that when doing so “office personnel must . . . articulate” that the field different from the Applicant’s “included a similar or analogous device (method, or product).” 72 Fed. Reg. at 57533. Because Johnson comes from a different field of endeavor than the Applicant’s, and because Johnson does not include an analogous method, a § 103 rejection based on Johnson is improper.

Johnson discloses an invention belonging to a different field of endeavor: “an apparatus for holding a first portion of bone and a second portion of bone together for the bone to heal.” Johnson at col. 1, ll. 40-42. The material properties of bone, for example density and durability, are significantly different than the soft tissue forming a heart septum. Because of the radical differences in the material properties of bone and heart septa, a person having ordinary skill in the PFO art would not look to the field of Johnson when trying to solve the problem of closing a PFO. Although Johnson states that the invention involves “the closure of hard or soft tissue,” Johnson at col. 1, ll. 5-10, the term “tissue” is explicitly limited in the Johnson specification: “[t]issue is defined as bone, muscle or fascia that has been divided to gain access the [sic]

*thoracic cavity, mediastinum, or abdomen.*” Johnson at col. 1, ll. 12-17. Because heart tissue is not something that is “divided to gain access” to one of the defined bodily areas, it is excluded by this definition; the necessary conclusion is that Johnson is a different field of endeavor.

Given that Johnson is in a different field of endeavor, in order for the reference to properly form the basis of a § 103(a) rejection it must be that the disclosed method is analogous to the Applicant’s. 72 Fed. Reg. at 57533. The Examiner has not shown that the methods are analogous, and more importantly, they are not analogous. The method of Johnson involves using a coil (“grommet”) 100 to line the interior of a hole or channel drilled in a bone. The coil in Johnson is functionally a sleeve, Johnson at col. 1, ll. 54-65, that is inserted into a channel drilled in a bone after which a suture is inserted through the sleeve. The method of using the radially expanding properties of coil to secure a sleeve inside a bone channel is not analogous to a method using the axial contracting properties of a coil to pinch together two flaps of heart tissue. In the former, the coil could be substituted for any sleeve capable of adhering with the sides of a channel in a bone regardless of whether it axially expands or contracts, whereas such a tubular shaped sleeve—without more—would not be successful in pinching shut a PFO.

Moreover, based on the significant differences between the method described by Johnson and the method described by Ginn as discussed above, one of ordinary skill in the art would not have found it predictable to make the modifications proposed by the Examiner. For these additional reasons, a § 103(a) rejection based on Johnson is inappropriate.

**3. Explicit Language In Ginn Teaches Away From The Applicant’s  
Invention in Claims 1, 20 and 31**

Since the Supreme Court’s oft-cited<sup>2</sup> decision in *United States v. Adams*, 383 U.S. 39 (1966), a showing that the prior art “teaches away” from the claimed invention has strongly favored a finding of nonobviousness.<sup>3</sup> Language in Ginn discourages inventing a device for closing a PFO that has the distal end of a coil releasably engaged with the distal end of an

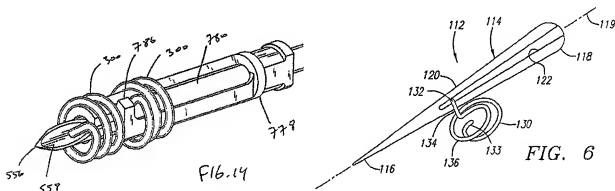
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<sup>2</sup> *Adams* is one of the “trilogy” of Supreme Court decisions (*Graham v. John Deere Co. and Calmar, Inc. v. Cook Chemical Co.*, 383 U.S. 1 (1966) being the other two) that, along with *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), form the touchstone for obviousness analysis.

<sup>3</sup> *E.g., in re Braat*, 16 U.S.P.Q.2d 1812 (Fed. Cir. 1990) (“One important indicium of nonobviousness is ‘teaching away’ from the claimed invention by the prior art.”).

elongate body. Ginn also teaches away from releasing the distal end of the coil from the tissue piercing structure.

The Examiner has characterized the Applicant's invention as having the "distal end of the coil being releasably engaged with the opening in the elongate body." Office Action at 4. This describes the portion of the coil and elongate body that enters the septa first when practicing one embodiment of Applicant's method; e.g., the portion of the coil that is engaged with the opening 558 in the figure below. See also Applicant's specification 206 of Fig. 2; Applicant's specification 312 of Fig. 6. The allegedly corresponding distal end of the Ginn coil 130 is the end 132 that is engaged with the needle 114. That structure, like the Applicant's, is the end of the coil that will enter the septa first when using the invention of Ginn. Reproduced below on the left is Applicant's Fig. 14; on the right is Ginn Fig 6.



Given this mapping of Ginn structure to the allegedly corresponding structure of the Applicant's invention, the following language in Ginn explicitly teaches away from the claimed invention: "[a] first end 132 of the filament 130 is substantially *permanently* attached to the intermediate region 120 [of the needle 114], e.g., by *bonding or welding* . . ." Ginn at p. 6, para. [0063] (emphasis added). In stark contrast, the Applicant's independent Claim 20 recites "a tissue piercing structure *releasably* engaged with the distal end of the coil," and independent Claim 31 similarly recites a "tissue piercing structure *releasably* engaging the distal end of the coil." Similarly, independent Claim 1 states: "the elongate body having a tissue piercing structure at its distal end and a coil releasably engaged with the elongate body." Because the quoted passage of Ginn unambiguously instructs that the distal end of the coil be permanently attached to the tissue piercing structure, one skilled in the PFO art would have been discouraged from inventing a device that involves doing just the opposite—releasing the distal end of the coil from



the tissue piercing structure. The Applicant's invention, embodiments of which are claimed in Claims 1, 20 and 31, created in the face of such teaching away, cannot fairly be characterized as obvious.

4. **Claims 1 and 31 Recite Additional Features Not Taught or Suggested by Ginn and Johnson**

Even assuming, without conceding, that Ginn and Johnson are properly combinable, not all the claimed structure or steps of the Applicant's claimed invention are suggested, disclosed, or taught by such a combination. The Examiner claims that "Ginn discloses . . . withdrawing the tissue piercing structure from the septa of the patent foramen ovale" as recited in Claim 1. Office Action at 3. This is a mischaracterization of Ginn. As already discussed in Part I.B.1 of this response, the tissue piercing structure of Ginn must stay implanted inside the heart in order for the invention to be operable. Thus, there is no reason that Ginn would disclose "withdrawing the tissue piercing structure from the septa of the patent foramen ovale." *Id.*

Further, the Examiner claims that "Ginn discloses . . . advancing the tissue piercing structure and the coil . . . through the septa of the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum first and then the septum secundum . . ." Office Action at 3 (emphasis added). This is also a mischaracterization of Ginn because the coiled portion of the Ginn filament 130 does not extend through the septa. This can be seen in Figs. 6 and 8B of Ginn reproduced above. Those figures demonstrate that it is only the straight portion 134 of the filament 130 that extends through the septa, and the coiled portion of the filament acts as a backing and does not extend into the septa. Language in Ginn also supports this assertion: "[i]n its unstressed or relaxed state, the filament 130 includes a *first* segment 134 that extends from the first end 132 *transversely*, and preferably substantially perpendicularly, to the longitudinal axis 119 . . . . [T]he *second* segment 136 is biased to define a planar configuration, e.g., in the shape of a coil, as shown in FIG. 6." Ginn at p. 6, para [0064] (emphasis added). In contrast to Ginn, Applicant's Claim 1 recites: "advancing the tissue piercing structure and the coil through the septa of the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum and the septum secundum." Similarly, Applicant's Claim 31 recites: "advancing the tissue piercing structure with the coil at least partially through the septa of the patent foramen ovale, wherein both the tissue piercing structure and the coil extend into the septum primum and the septum secundum."

Therefore, for at least the reasons set forth above, Applicant submits that Ginn in view of Johnson does not render independent Claims 1 or 31 obvious. The foregoing references, when viewed alone or in combination, do not disclose, teach, or suggest each and every element of the claimed invention.

**C. Dependent Claims 2-10, 21-25, and 32-35 Recite A Unique Combination of Features Not Taught or Suggested by the Cited Art**

The outstanding Office Action rejected dependent Claims 2-10 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Johnson. Claims 2-10 depend from Claim 1 and further define the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, as well as the lack of any explained rationale to combine Ginn in view of Johnson, Applicant respectfully submits that Claims 2-10 are patentable over Ginn in view of Johnson. Claims 2-10 are also patentable over Ginn in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 2-10 based on Ginn in view of Johnson.

The Office Action also rejected dependent Claims 21-25 under § 103(a) as being unpatentable over Ginn in view of Johnson. Claims 21-25 depend from Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20, Applicant respectfully submits that Claims 21-25 are patentable over Ginn in view of Johnson. Claims 21-25 are also patentable over Ginn in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 21-25 based on Ginn in view of Johnson.

The Office Action further rejected dependent Claims 32-35 under § 103(a) as being unpatentable over Ginn in view of Johnson. Claims 32-35 depend from Claim 31 and further define the invention of Claim 31. For at least the reasons set forth above with respect to Claim 31, Applicant respectfully submits that Claims 32-35 are patentable over Ginn in view of Johnson. Claims 32-35 are also patentable over Ginn in view of Johnson because of the additional limitations recited in each respective claim. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 32-35 based on Ginn in view of Johnson.

**D. Dependent Claims 27-30 Recite A Unique Combination of Features Not Taught or Suggested by the Cited Art**

The outstanding Office Action rejected dependent Claims 27-30 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Johnson. Claims 27-30 depend from Claim 20 and further define the invention of Claim 20. For at least the reasons set forth above with respect to Claim 20 as well as the lack of any explained rationale to combine Ginn in view of Johnson, Applicant respectfully submits that Claims 27-30 are patentable over Ginn in view of Johnson.

Moreover, in rejecting Claims 27-30, the Examiner has mischaracterized the invention of Ginn: “Ginn discloses the coil having a tang (133 on the distal end and 132 on the proximal end) that extends into a diameter defined by the coil . . . .” Explicit language in Ginn is to the contrary: “[T]he first *end* 132 is attached within or adjacent to the slot 122, and a second *end* 133 of the filament 130 is loose.” Ginn at p. 6, para. [0063]. The quoted language makes clear that 132 and 133 are not tangs but merely references to the ends of the coil. Further, by focusing on the functionality of Ginn, it is clear that there is no reason for end 132 of the coil to include a tang. The tangs on the ends of the Applicant’s coil in one embodiment are used to releasably engage with the tissue piercing structure and loading portion. Because Ginn instructs that end 132 should be “substantially permanently attached” to the tissue piercing structure via means such as “bonding or welding,” *id.*, Ginn would have no reason to disclose a distal tang for releasably engaging with the tissue piercing structure.

Finally, with respect to Claim 30, the Examiner admits that “a plurality of coils on the loading portion is not disclosed” by Ginn in view of Johnson. Office Action at 5. However, the Examiner makes the following conclusory remark: “it would have been obvious to one of ordinary skill in the art to modify the loading portion of Ginn to accommodate multiple coils in order to further secure the septum primum and septum secundum together.” *Id.* The Examiner has failed to explain *why* one skilled in the art would have found it obvious to use a plurality of coils, and has not provided any evidence supporting the obviousness finding, either in another reference or based on the knowledge or common sense of one having ordinary skill in the art.<sup>4</sup> In

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<sup>4</sup> 72 Fed. Reg. at 57528 (“The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.”).

light of the prior art limiting itself to the use of a single coil, it would not have been obvious to use a plurality of coils to close a PFO.

**E. Claims 11 and 12 Are Not Rendered Obvious over Ginn in view of Johnson in further view of Pierson, III ("Pierson") (U.S. Patent No. 6,663,633)**

**1. Ginn and Johnson Are Not Properly Combinable**

The Office Action lists Claims 11-15 and 17-19 as being rejected under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Johnson in further view of Pierson. Claim 11 depends from Claim 1 and further defines the invention of Claim 1. For at least the reasons set forth above with respect to Claim 1, Applicant respectfully submits that Claim 11 is patentable over Ginn in view of Johnson. The outstanding Office Action rejects independent Claim 12 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Johnson in further view of Pierson. The necessary implication from this rejection is that Ginn and Johnson are properly combinable—Applicant respectfully disagrees. In particular, with respect to Claims 11 and 12, the Examiner asserts that “Ginn and Johnson disclose the claimed invention except for advancing a second coil releasably engaged with the elongate body through the septa of the patent foramen ovale at a location adjacent to the first coil and releasing the second coil from the elongate body, wherein the second coil when released contracts to pinch the septum primum and the septum secundum.” Office Action at 5. As explained above in Part I.B.1, Ginn and Johnson are not properly combinable. Without completely revisiting that argument, the essential point is that Ginn would be inoperable for its intended purpose if modified as suggested by the Examiner. Thus, for at least the reasons set forth in that part of this response, Applicant respectfully submits that Claims 11 and 12 are patentable over Ginn in view of Johnson in further view of Pierson.

**2. Claim 12 Recites A Unique Set of Steps Not Taught or Suggested by Ginn in view of Johnson in further view of Pierson**

Even assuming, without conceding, that Ginn and Johnson are properly combinable, not all the claimed steps of the Applicant's method recited in Claim 12 are suggested, disclosed, or taught by Ginn in view of Johnson in further view of Pierson.

Pierson teaches placing an insertion element 20 across a tear, then inserting a helix or suture 12 into the lumen 21 of the insertion element, and finally removing the insertion element from the tear thereby leaving the helix in position across the tear. Pierson at col. 7, ll. 61-76, col. 8, ll. 1-8. After describing these steps, the Pierson specification then states—without further

explanation—that “a plurality of helical devices 12 may be used to repair a unitary tear 91 (FIG. 1E).” Pierson at col. 8, ll. 12-13. This conclusory statement is the extent of Pierson’s teaching with regard to using a plurality of coils to close a tissue tear. Such a statement cannot be fairly characterized as a suggestion of *how* the combination of Ginn and Johnson would be modified to use a plurality of coils.<sup>5</sup> In particular, because Ginn requires that the tissue piercing structure remain inside the heart in order for it to function, see Part I.B.1, it would not be obvious to one skilled in the PFO art, in view of Ginn, Johnson, and Pierson, how the Ginn and Johnson combination could be modified with Pierson to insert a second coil.

More importantly, even if a person of ordinary skill could combine Ginn, Johnson, and Pierson, Claim 12 recites several steps not taught or suggested—let alone rendered obvious—by this combination. Claim 12 recites, *inter alia*, “releasably engaging a plurality of discrete implantable coils with a single delivery device, the single delivery device comprising a tissue piercing structure.” The combination does not suggest how a plurality of coils could be releasably engaged with a single delivery device—Pierson cursorily states that a plurality of coils “may be used.” Pierson at col. 8, ll. 12-13. Claim 12 also recites “retracting the tissue piercing structure proximally to engage an additional coil without removing the tissue piercing structure from the body of the patient.” Again, the Examiner’s cited combination does not suggest *how*, upon retracting the tissue piercing structure, an additional coil would be engaged with the tissue piercing structure without removing the tissue piercing structure from the body of the patient. Accordingly, Applicant submits that Claim 12 is allowable over the combination of Ginn in view of Johnson in further view of Pierson.

**F. Dependent Claims 13-15, and 17-19 Are Not Rendered Obvious over Ginn in view of Johnson in further view of Pierson**

The outstanding Office Action rejected dependent Claims 13-15 and 17-19 under 35 U.S.C. §103(a) as being unpatentable over Ginn in view of Johnson in further view of Pierson. Claims 13-15 and 17-19 depend from Claim 12 and further define the invention of Claim 12. For at least the reasons set forth above with respect to Claim 12, Applicant respectfully submits

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<sup>5</sup> *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”), *cited with approval in KSR*, 127 S. Ct. at 1741.

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Filed : February 20, 2004

that Claims 13-15 and 17-19 are patentable over Ginn in view of Johnson in further view of Pierson. Claims 13-15 and 17-19 are also patentable over Ginn in view of Johnson in further view of Pierson because of the additional limitations recited in each respective claim.

### III. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

### IV. Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial Number | Title  | Filed      | Matter Reference |
|---------------|--|------------|------------------|
| 11/584828     | TISSUE OPENING OCCLUDER  | 10/23/2006 | EV3.062DV1       |
| 11/607237     | TISSUE OPENING OCCLUDER  | 11/30/2006 | EV3.062DV2       |
| 11/927448     | TISSUE OPENING OCCLUDER  | 10/29/2007 | EV3.062C1        |
| 10/419412     | SEPTAL DEFECT OCCLUDER   | 4/21/2003  | EV3.058CPC1      |
| 10/227773     | DEFECT OCCLUDER RELEASE ASSEMBLY AND METHOD  | 8/26/2002  | EV3.059C1        |
| 12/110186     | RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE   | 4/25/2008  | EV3.067C1C1      |
| 10/972635     | PATENT FORAMEN OVALE CLOSURE SYSTEM  | 10/25/2004 | EV3.079A         |
| 10/771845     | PATENT FORAMEN OVALE CLOSURE SYSTEM  | 2/4/2004   | MVMDINC.019A     |
| 10/841880     | DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT | 5/7/2004   | MVMDINC.068A     |

Appl. No. : 10/783,783  
Filed : February 20, 2004

V. Conclusion

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, she is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

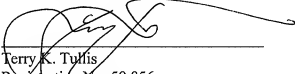
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6-24-08

By: \_\_\_\_\_

  
Terry K. Tullis  
Registration No. 59,856  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

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